EXPRESS MAIL NO. EV335392699US



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Martin A. Cheever and Mary L. Disis

Application No.

09/167,516

Confirmation No.

1422

Filed

October 06, 1998

For

COMPOUNDS FOR ELICITING OR ENHANCING IMMUNE

REACTIVITY TO HER-2/neu PROTEIN FOR PREVENTION OR TREATMENT OF MALIGNANCIES IN WHICH THE HER-2/neu

ONCOGENE IS ASSOCIATED

Examiner

Karen A. Canella, Ph.D.

Art Unit

1642

Docket No.

920010.448C8

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner:

I, Martin A. Cheever, hereby declare as follows:

- 1. Mary L. Disis and I are coinventors of the subject matter described in the above-identified patent application (hereinafter referred to as "subject application").
- 2. I hold an M.D. and was employed at the time the subject application was filed by the University of Washington where I held the position of Professor of Medicine, Division of Medical Oncology. I am presently employed by Corixa Corporation of Seattle, Washington.
- 3. I have been involved in immunology for over 25 years and I have authored or coauthored about 100 publications in this field. My research specialty is immunology related to cancer.
- 4. I am a co-author of the article appended hereto: Foy et al., Vaccine 19:2598-2606, 2001 (hereinafter referred to as "the article").

5. Figure 1 at page 2600 of the article shows that vaccination of mice with a

plasmid expressing ICD polypeptide (intracellular domain of HER-2/neu protein) is effective to

prevent growth of HER-2/neu tumor.

6. The results shown in Figure 1 of the article necessarily mean that

sufficient polypeptide is expressed by the plasmid DNA encoding ICD polypeptide to generate

an efficacious immune response.

7. The sentence beginning at the end of page 2603 and completed at the top

of page 2605 of the article states: "Taken together, these data provide strong evidence to suggest

that protective immunity to Her-2/neu can be elicited by vaccination, demonstrating its utility as

a cancer vaccine target."

8. Thus, the results presented in the article confirm the teachings of the

subject application that administration to a warm-blooded animal of DNA or plasmid expressing

ICD polypeptide of HER-2/neu protein achieves transient expression to the extent necessary to

generate an efficacious immune response.

9. I further declare that all statements made herein of my own knowledge are

true and that all statements made on information and belief are believed to be true; and further,

that these statements were made with the knowledge that the making of willfully false statements

and the like is punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code, and may jeopardize the validity of any patent issuing from this patent

application.

Dated this 3 / day of July, 2004.

Martin a. Chem

Martin A. Cheever

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TRANSMITTAL FORM

(To be used for all correspondence after initial filing)

Application Number	09/167,516	
Filing Date	October 06, 1998	
First Named Inventor	d Inventor Martin A. Cheever	
Art Unit	1642	
Examiner Name	CANELLA, Karen A.	
Attorney Docket No.	920010.448C8	

ENCLOSURES (check all that apply)				
Cited Referen Certified Copy Document(s) Response to I under 37 C.F. Response to I	al Form hed Response I aration Time Request donment sclosure orm PTO-1449 ces of Priority Missing Parts R. 1.52 or 1.53	Drawing(s) Request for Corrected Filing Receipt Licensing-related Papers Petition Petition to Convert to a Provisional Application Power of Attorney, Revocation, Change of Correspondence Address Declaration Statement under 37 CFR 3.73(b) Terminal Disclaimer Request for Refund	CD(s), Number of CD(s) After Allowance Communication to Group Appeal Communication to Board of Appeals and Interferences Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) Proprietary Information Status Letter Return Receipt Postcard Additional Enclosure(s) (please identify below):	
Remarks				
Individual Name	SIGNATURE OF APPLICANT, ATTORNEY, (Richard G. Sharkey, Ph.D. Registration No. 32,629		OR AGENT Customer Number 00500	
Signature RISQ Muly				
Date Augan 17 2004				
) VIA EVENESS MAIL				
VIA EXPRESS MAIL				

MillicentS/509089



RESPONSE UNDER 37 C.F.R. § 1.116 EXPEDITED PROCEDURE - EXAMINING GROUP 1640

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Martin A. Cheever and Mary L. Disis

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For

COMPOUNDS FOR ELICITING OR ENHANCING IMMUNE REACTIVITY TO HER-2/neu PROTEIN FOR PREVENTION OR TREATMENT OF MALIGNANCIES IN WHICH THE HER-2/neu

ONCOGENE IS ASSOCIATED

Examiner

CANELLA, Ph.D., Karen

Art Unit

1642

Docket No.

920010.448C8

Date

August 18, 2004

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Commissioner:

Further to the Reply and Amendment submitted on July 27, 2004, please find enclosed the Declaration executed by inventor Martin A. Cheever under 37 C.F.R. § 1.132.

Respectfully submitted.

SEED Intellectual Property Law Group PLLC

Richard G. Sharkey, Ph.D. Registration No. 32,629

Customer Number 00500

Enclosure:

Declaration of Martin A. Cheever under 37 C.F.R. § 1.132

MillicentS/509079